
NTP-CERHR

Proposed Small Datasets Process

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CERHR Output from June 1998 to September 2004

- 14 Expert Panel Reports
- 12 NTP-CERHR Monographs (DEHP and Acrylamide Briefs pending in-house review)

Factors Considered for Chemical Selection

- Public Concern
- Human Exposure
- Reproductive and Developmental Toxicity Data
- Production Volume

Chemical Nominations

- 381 (9/04) reviewed by Core Committee
- 20 chemicals selected for expert panel evaluation
- 50 chemicals deferred
 - some of public interest, but with too few data for an expert panel meeting

Examples of Large Datasets

Acrylamide Expert Panel Report

**Developmental Toxicology - 12 studies
(12 animal, 0 human)**

**Reproductive Toxicology - 18 studies
(18 animal, 0 human)**

Fluoxetine Expert Panel Report

**Developmental Toxicology - 46 studies
(20 animal, 26 human)**

**Reproductive Toxicology - 31 studies
(16 animal, 15 human)**

Examples of Small Datasets (SDS):

Dimethyl-methylphosphonate (DMMP)

**Developmental Toxicology - 2 studies
(2 animal, 0 human)**

**Reproductive Toxicology - 6 studies
(6 animal, 0 human)**

Di-ethylphthalate (DEP)

**Developmental Toxicology - 3 studies
(3 animal, 0 human)**

**Reproductive Toxicology - 2 studies
(2 animal, 0 human)**

Parabens [methyl, ethyl, propyl, butyl]

**Developmental Toxicology - 4 studies
(4 animal, 0 human)**

**Reproductive Toxicology - 7 studies
(8 animal, 0 human)**

Differences between SDS Process and Expert Panel Process

- Draft report written by CERHR
- Draft report reviewed by experts
- No Public Meeting; 3 public comment periods rather than 4
- No NTP Monograph or NTP Brief; NTP executive summary a part of the peer-reviewed report; public comments on the report appended to the final report

Similarities between SDS Process and Expert Panel Process

- Chemical nomination and selection process identical
- Expert reviewers selected from CERHR Expert Registry
- CERHR guidelines followed
- Report format same as Expert Panel Report

Advantages of SDS Process

- **Provide information on chemicals with high public interest and identify data needs**
- **Increase the number of chemicals evaluated by CERHR**
- **Fewer time constraints than an Expert Panel Evaluation**

Final Product

“NTP-CERHR Small Data Set Report on the Reproductive and Developmental Toxicity of _____”

- **NTP Executive Summary**
- **Small Dataset Report**
- **Public Comments on the Report**